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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,663	04/02/2004	Dale E. Shuster	2003.027 US / AH06021US01	1036
24265 7590 06/17/2008 SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 06/17/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/816,663	Applicant(s) SHUSTER ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 17-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicants' exhibits and remarks submitted March 7, 2008 is acknowledged.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beuvry et al. (US 6,653,288, IDS) in view of Komer (US 5,773,422) and Apelian et al. (US 5,082,863), and in further view of Ogunrinade et al.

3. Beuvry et al. teaches ivermectin is an old and well-known anthelmintic agent and is particularly useful for animals, such as cattle. Beuvry et al. further teach an injectable composition comprising ivermectin and pharmaceutical acceptable carrier(s), wherein the amount of the anthelmintic agent is about 0.2 to 20 % wt %, and suitable carriers (solvent) includes propylene glycol, polyethylene glycol, pyrrolidone etc. Beuvry et al. further teach the composition may further comprise an antibiotic. See, particularly, the claims.

Beuvry et al. do not teach expressly a combination forfenicol and ivermectin, or the particular pharmaceutical acceptable carriers.

4. However, Apelian et al. teach that forfenicol is a known antibacterial agent and is particularly useful for veterinary purposes. Apelian et al. further teaches an injectable composition comprising 10-50% of forfenicol and 2-pyrrolidone (or N-methyl-2-pyrrolidone), propylene glycol and polyethylene glycol as the carrier. See, particularly the examples and the

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claims. Komer discloses that pyrrolidone such as 2-pyrrolidone and N-methyl-2-pyrrolidone are particularly known to be useful as solvent in ivermectin composition. See, particularly, the abstract and the claims. Ogunrinade et al. disclose that immunodepression is known to accompany parasitic disease, and co-infection of parasite and bacteria are known in the art. See, page 121.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a composition comprising ivermectin and forfenicol for treatment of animal infected by parasite and bacteria.

A person of ordinary skill in the art would have been motivated to make a composition comprising ivermectin and forfenicol for treatment of animal infected by parasite and bacteria because ivermectin and forfenicol are known to be useful against parasite and bacteria respectively. Further, animals are known to have both parasitic infection and bacterial infection. Further it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a composition with the particular concentration and carriers, as the concentrations are within the known range of the prior art and the carriers are all known to be useful with ivermectin and forfenicol. Furthermore, Beuvry et al. teaches that ivermectin composition may comprise antibiotics.

Response to the Arguments

Applicants' exhibits and remarks submitted March 7, 2008 have been fully considered, but are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

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combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Particularly, ivermectin is a old and well-known anthelmintic agent and is particularly known to be used together with an antibiotics in injectable formulation. that forfenicol is an old and well-known antibiotics and is known to be used in injectable formulation. Further more, co-infection of parasite and bacteria are known in the art. Therefore, considering the prior art as a whole, the claimed invention would have been obvious.

Applicants' remarks that drugs may react each other and such reaction would discourage skilled artisan from using a combination of two drugs. These arguments are untenable. As applicants admitted, some drugs may interact and some don't. Selection of a proper combination through a routine experimentation is within the skill of artisan and is obvious.

“When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. **If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.** See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1397 (2007).

5. Applicants' remarks about Ogunrinade et al. is not persuasive. Note it is a fact that animals are co infected with parasite and bacteria. Further, the cited references have to be considered as a whole. Note, Beuvry et al. teaches the concomitant of anthelmintic and antibiotics.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shengjun Wang/
Primary Examiner, Art Unit 1617